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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/331,262	06/13/99	PEREGRINO FERREIRA	P 41826

HM12/1021

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EXAMINER	
ZEMAN, R	
ART UNIT	**PAPER NUMBER**
1643	6

DATE MAILED: 10/21/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/331,262	Ferreira Et. Al.
Examiner	**Group Art Unit**
Robert A Zeman	1643

☒ Responsive to communication(s) filed on *Jun 13, 1999* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-3* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-3* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *5*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claim Objections

Claim 1 is objected to because of the following informalities: Claim does not end with a period. Additionally, Claim 1 recites the word "unbounded" which is not idiomatic English. It is suggested that "unbound" be used instead of "unbounded". Appropriate correction is required.

Specification

The disclosure is objected to because of the following informalities:

1. The specification refers to Figure 4 (See page 5 line 25). No drawing labeled as figure 4 was submitted.

2. Additionally, the sentence "....or beads followed by eletrotransferred or transferred passively in the these concentrations to nitrocellulose or nylon supports." (See page 6 lines 4-6) is confusing and illogical.

Appropriate corrections are required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention employs the use of a recombinant p26 protein. The specification does not set forth procedures for obtaining or making p26 recombinantly. The specification is completely lacking in the disclosure of appropriate sequences, vectors, expression systems or procedures for making a recombinant p26 protein usable in the invention. One of ordinary skill in the art would not be able to follow the procedures set forth in the specification to make and use the invention as claimed with a reasonable expectation for success and without undue experimentation based on the scanty guidance provided in applicant's specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite since step (a) does not describe an active process. Changing "the use of" to "providing" is suggested. Additionally, the final step of the process as described in (f) does not correlate with the preamble of the claim. "Detecting the presence of...." is not equivalent with

"measuring amount of.....". Additionally, the terms "protein" and "antigen" are used interchangeably in Claim 1. It is unclear whether the applicant is claiming the entire p26 protein or merely an antigenic epitope of the p26 protein.

Claims 2 and 3 are rejected as they recite improper Markush language, rendering the claim indefinite. Proper language for claim 2 would be "....label is selected from the group consisting of an enzyme, a fluorescent marker **and** biotin marker."

Claim 3 is confusing. There is no logical grouping or delineation between the listing of the various solid supports and the materials of which they are comprised.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 recite an immunoenzymatic assay for detecting antibodies to Equine Infectious Anemia Virus (EIAV).

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porter et al. (U.S. Patent 4,806,467) and Shen et al. (American Journal of Veterinary Research Vol 45(8) pp 1542-1543) in view of Peterson et al. (U.S. Patent 5,427,907) and Reis et al. (Reis et al, 1996 GENBANK ACC. NO.U53452).

Both Porter et al. and Shen et al. disclose assays that use purified native p26 as the bound antigen for the detection of antibodies to EIAV. Both disclose the procedures for binding the p26 antigen to a solid support; for reacting the bound antigen with a test sample of serum; for removal of unbound test sample; for reacting bound test antibody with a labeled conjugate; and for the measurement of bound antibody to EIAV p26. Neither Porter et al. nor Shen et al teach the use of recombinant p26 as the bound antigen. Peterson discloses an assay for detecting EIAV using recombinant gp45. Peterson et al. used recombinant gp45 in the assay because the technique of culturing a virus increases the likelihood that the assay would yield false positive results since the virus may be contaminated with other forms of protein. Additionally the EIA virus is hard to culture making the Porter et al approach difficult for large scale production.

Peterson et al disclose an assay for the detection of the EIA virus which can be quickly and easily performed using a pure source of antigen thus reducing the problem of false positive results. Peterson et al. however does not disclose the use of recombinant p26. Reis et al. (Reis et al, 1996 GENBANK ACC. NO. U53452), however, disclose the sequence for a recombinant p26 antigen . Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the recombinant p26 disclosed by Reis et al in the EIAV detection assay of Porter et al. and Shen et al. because recombinant EIAV protein offers a safer and more pure form of the protein as disclosed by Peterson et al.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032.

Art Unit: 1643

DONNA WORTMAN
PRIMARY EXAMINER

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October 20, 1999